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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,115

12/15/2005

Norikazu Ohtake

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EXAMINER

JARRELL, NOBLE E

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,115	<b>Applicant(s)</b> OHTAKE ET AL.	
	<b>Examiner</b> Noble Jarrell	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I in the reply filed on 3/24/2008 is acknowledged.

### ***Claim Objections***

2. Claims 35-43 are objected to because of the following informalities: Phrases such as "(excepting a methyl group)" are considered improper in claims. In each of these claims, one or more parenthesized expressions are present. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 35-44 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for instances where variable R is phenyl, O-phenyl, naphthyl, quinoliny, 4-oxo-1,3-diazole, piperidin-2-one, pyridine, pyridin-2-2(1H)-one, dialkylamino, pyrimidine, [1,2,4]-triazolo[4,3-a]pyridine, dibenzo[b,d]furan, and CH<sub>2</sub>-piperidiny, does not reasonably provide enablement for the other possible groups disclosed for variable R in these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants only provide support for compounds where variable R is phenyl, O-phenyl, naphthyl, quinoliny, 4-oxo-1,3-diazole, piperidin-2-one, pyridine, pyridin-2-2(1H)-one, dialkylamino, pyrimidine, [1,2,4]-triazolo[4,3-a]pyridine, dibenzo[b,d]furan, and CH<sub>2</sub>-

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piperidinyl. In claim 35, the scope of the variable R encompasses much more than the disclosure reasonably enables.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to compounds of formula I that are defined by a pyrimidine-O-piperidine core and pharmaceutical compositions containing same. This core only defines 50% of the molecule. The presence and identity of variables Y and R are critical to this compound and may even alter the substantial structural core and thus alter the classification of the compound itself.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

Compounds encompassed by formula I are known in the art. Dorwald (*Side Reaction in Organic Synthesis*, **2005**, page IX of preface) teaches that organic chemistry is difficult.

*(5) The relative skill of those in the art:*

One of ordinary skill in the art can replicate example 1 of the specification.

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*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided guidance for the preparation of compounds of formula I where variable R is phenyl, O-phenyl, naphthyl, quinoliny, 4-oxo-1,3-diazole, piperidin-2-one, pyridine, pyridin-2-2(1*H*)-one, dialkylamino, pyrimidine, [1,2,4]-triazolo[4,3-*a*]pyridine, dibenzo[*b,d*]furan, and CH<sub>2</sub>-piperidinyl.

However, the specification does not provide guidance how to make and use all of the possible modificationa encompassed by variable R set forth in the claim .

*(8) The quantity of experimentation necessary:*

Considering the state of the art as discussed by the references above, particularly with regards to claims 38-44 and 46-47 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 35-38 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Marino et al. (WO 2005/097111, published October 20, 2005, filed March 22, 2005, claiming priority back to 60/561,188, filed 9 April 2004, cited i June 21, 2007 office action). Claims 35-38 and 45 are anticipated by Marino et al. because they teach the first species of claim 45, 2-(1-cyclopentylpiperidine-4-yloxy)-5-(4-cyanophenyl)pyrimidine (see page 6, line 14). The elected species has the following meaning for each variable: Y is 4-cyanophenyl; X<sub>1</sub> and X<sub>2</sub> are N; X<sub>3</sub> is C; W is formula II where m=1; and R is cyclopentyl. Claims 46 and 47 are anticipated because Marino et al. also discuss compositions comprising this compound on page 8 from lines 6-19.

### **Conclusion**

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**